

ADVANCE Project Sustainability Plan

Business Model Canvas

This project receives funding from the European Union's Erasmus Plus programme under grant agreement 019-1-NL01-KA203-060286. This publication reflects the views of the author only; the European Commission cannot be held responsible for any use which may be made of the information contained herein.



Executive Summary

❖ Context

Advanced therapy medicinal products (ATMPs) offer ground-breaking new therapeutic opportunities for numerous diseases, however the translation from research into patient access is beset by many challenges and needs to involve many stakeholders.

For ATMPs to fulfil their full potential, specific skills and knowledge need to be available in the workforce. Since early career biomedical scientists are considered to be an important component of the labour market and the critical intermediaries of the ATMP development pipeline, it is essential to educate the next generation of ATMP professionals.

❖ Mission

The ADVANCE programme strives to educate the next generation of ATMP experts. The ADVANCE blended learning programme supports early-career biomedical professionals in acquiring and developing technical and transversal skills and key competences in four key challenge areas – manufacturing, clinical trials, regulatory approval and reimbursement.

❖ Outputs and activities

The blended programme consists of an online course and a 5 day workshop and an online course. The online course is self-paced, open to everyone and completely free of charge. The 5-day workshop focuses on all aspects of ATMPs development. The curriculum is complemented by group work assignments and networking activities.

❖ The market

The “next generation of ATMP developers” – i.e. early-career biomedical academics (PhDs, Postdocs), including doctors in training, clinician-scientists and SME-based professionals, who are considered to be an important component of the labour market and the critical intermediaries of the ATMP development pipeline – are the core target group for the blended learning programme foreseen by ADVANCE.

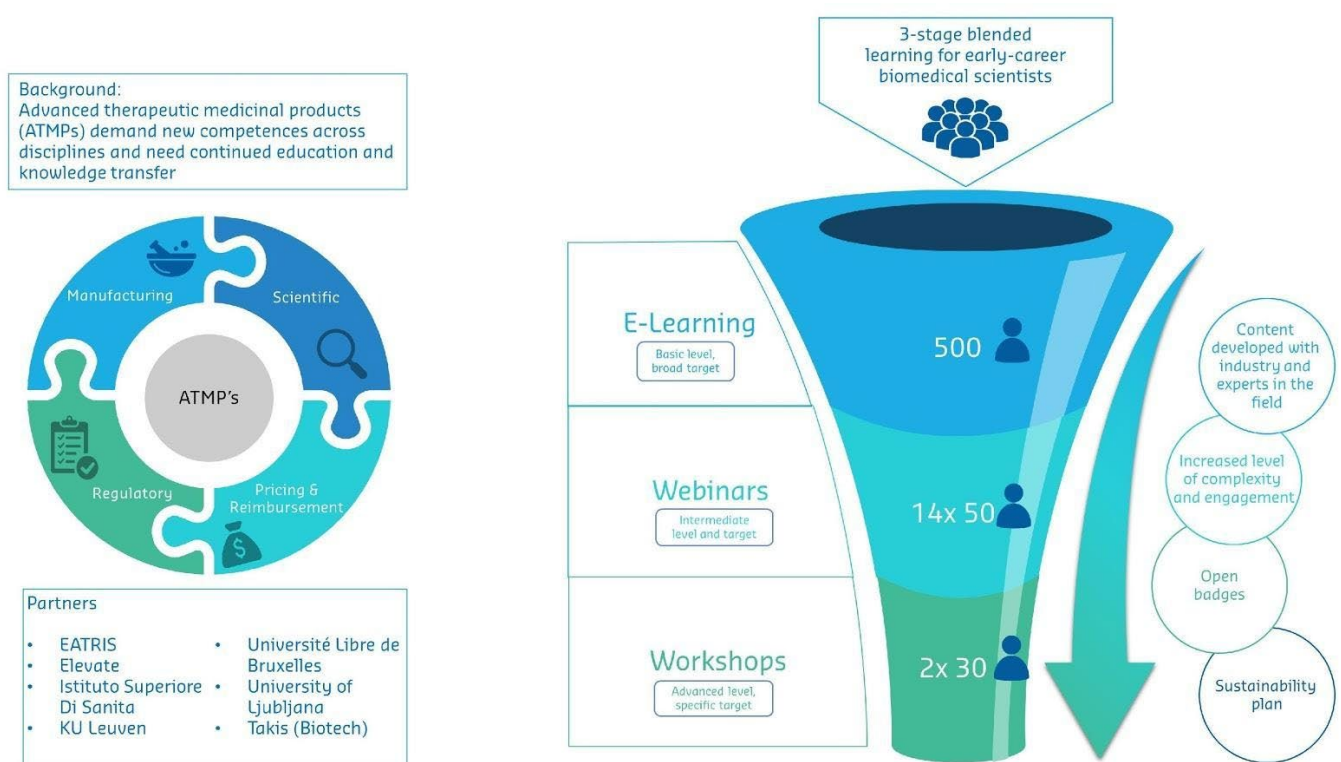
❖ Legal framework and ownership

The ADVANCE Consortium is a strategic partnership between 7 European key players in the field of ATMPs from education, research and industry. After the end of the ADVANCE project, the programme will be rebranded as the “Cell and Gene Therapy Summer School.” For the organisation of the next editions of the 5-Day Workshop, a new model, based on joint ownership and a rotational organization between the new consortium members was set up. To ensure the provision of the online course free of charge, ownership of the online curriculum has been transferred to a single owner regime.

❖ Financial model

This sustainability plan describes how the face-to-face courses and the online course can be maintained in a way that enables a broad participation and reduces the costs for participants. The yearly cost of the Cell and Gene Therapy Summer school is evaluated at 21.000 Euros (see

cost breakdown in Annex 3). To cover these costs, workshop participants will be charged with a registration fee (see payment scheme laid out in Section 3 below), and a biotech/pharma company will be sought out to host the workshop in order to lower costs. Additionally, the consortium will seek out external funding and grants. The aim is to achieve financial sustainability of the programme, and not to generate profits. Any extra funds will be invested into the next edition of the programme.



Contents

Executive Summary.....	2
1. The ADVANCE Programme	5
1. Objectives.....	5
2. Intellectual Outputs	7
3. Value Proposition.....	8
4. Marketing strategy.....	9
2. Risks and quality assurance	15
3. The Sustainability Plan	17
1. Business organisation	17
a. Role of the consortium partners	17
b. Resources/support	17
c. New learner's journey	18
d. Legal framework and ownership	19
2. Cost structure.....	19
a. Mixed financing of the workshop and online course	20
b. Payment schemes (industry vs academia).....	21
c. Hosting and financial support of the workshop	21
3. Business opportunities and partnerships	21
4. Conclusion.....	22
5. Annexes	23
Annex 1: Dissemination and Communication Plan.....	23
Annex 2: Market analysis.....	23
Annex 3: Cost breakdown	23

1. The ADVANCE Programme

1. Objectives

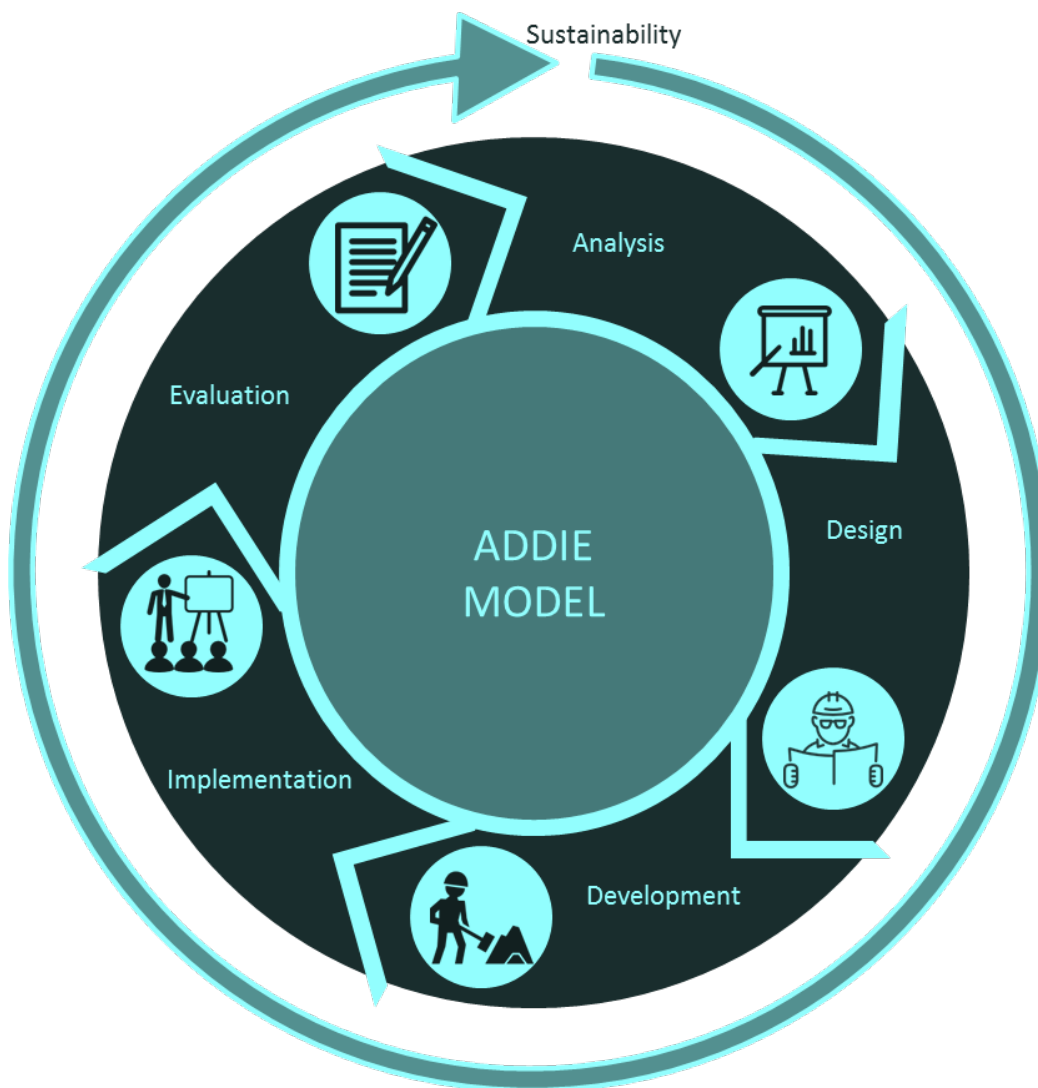
The ADVANCE Project is a 30-month European training project supported by the Erasmus+ programme, with the overall objective of bringing together stakeholders from different sectors and disciplines to develop a course targeted at PhD students and young postdocs, transferring the skills and competencies required to successfully contribute to ATMP development. ADVANCE consortium is led by the European Infrastructure for Translational Medicine (EATRIS) in The Netherlands, and consists of 6 additional European partners: Elevate Health (The Netherlands), Istituto Superiore di Sanità (ISS, Italy), Institute for Interdisciplinary Innovation in healthcare (I3h, Université libre de Bruxelles, Belgium), KU Leuven (Belgium), Takis Biotech (Italy), and University of Ljubljana, Faculty of Pharmacy (UL FFA (Slovenia).

To ensure that the course indeed transfers the skills needed and relevant for the labour market, be it in academia, industry or the regulatory field, the course curriculum is based on previously established [competency profile](#) and [characteristics](#) for scientists involved in (translational) medicine research and development. The course is delivered as a blended-learning course: e-learning modules aimed at bringing the participants to a common level of knowledge, webinars for furthering the scientific knowledge exchange in the 4 key challenge areas existing in ATMP development and career progression advice, followed by the face-to-face course week, wherein more in-depth knowledge is envisaged, through active course participation, group work, in-depth discussions and an ATMP manufacturer's visit.

The methodology to develop the courses and used to maintain the high quality in the years following the European support for the ADVANCE Project was the ADDIE principle. ADDIE stands for the different steps needed to prepare an effective learning session and was implemented in this project accordingly:

1. During the analysis phase, learning objectives of the courses have been defined based on a previously established competency profile and characteristics for scientists involved in (translational) medicine research and development, to ensure match with labour market needs. Both resources include not only the scientific competencies required to be successful in the field of medicines development, particularly Advanced therapeutics, but also transversal skills and entrepreneurship.
2. During the design phase, the consortium designed and documented curricula for the online course, the webinars and the workshop based on the established learning objectives and previously defined competences. The curriculum applies multi-competency training combining the acquisition of in-depth multidisciplinary scientific knowledge with the development of personal and transversal skills (e.g. communication, project management, career strategy and entrepreneurial skills) to help participants boost their confidence and prospects in the labour market.

3. During the development phase, the course content was designed including learning methods which promote the transfer of course content into observable competencies and cater for different learning styles.
4. The implementation phase consisted of the deployment and running of the e-learning module, the technology based and career skills webinars, career coaching sessions and the face-to-face course.
5. For the evaluation phase feedback was used to optimise the next iterations of the e-learning, webinars and face-to-face course.



The unique value proposition is therefore to support young scientists to develop the crucial skills and competencies needed to contribute towards the creation of innovative and highly complex medicines and therapies (Advanced Therapy Medicinal Products or ATMPs). We provide hands-on, ready-to-use learning activities which complement the academic/scientific background present in our target population. During the 30-month project, we developed a three-stage blended learning programme consisting of 3 complementary and interconnected modules - all addressing key challenging areas in ATMP development: online course (basic

scientific knowledge); webinars (in-depth scientific knowledge and skills), combined with career coaching and face-to-face workshops (training transversal skills and competences). The learning objectives address the general competencies such as basic knowledge, skills and behaviour considered essential for biomedical PhD students and postdocs involved in ATMP development.

Several national and European initiatives have explored and identified major gaps in ATMP development, specifically with respect to manufacturing, clinical trials, regulatory and reimbursement issues.

The objectives of the project are therefore to advance ATMP product development in Europe by developing training targeting the critical intermediaries in the ATMP development pipelines (PhDs, postdocs, young MDs and professionals).

By educating the next generation of European ATMP professionals, we aim to maintain and expand Europe's leadership in the biotechnology field, with the ultimate goal to improve human health; an outcome that benefits the entire society. The project is carried out transnationally since the ATMP market is a Pan-European market with stakeholders distributed across Europe.

2. Intellectual Outputs

The project has generated 5 different intellectual outputs:

1. [Online course \(IO1\)](#) - The online course is open and free of charge to anyone interested in the ATMPs development topic. The course is ca. 8 hours of interactive lectures, and nearly 20 hours of independent assignments, and is entirely self-paced. It consists of 4 Units representing the key challenges of the ATMPs development cycle – Scientific, Manufacturing, Reimbursement and Regulatory. The online course will be sustained after the project and will be available via EATRIS' Learning Management system (TransMed Academy) and will be freely accessible upon registration to the platform. It will be a prerequisite for participating in the workshops. More details are provided in the 3rd part of the plan.
2. [Webinars \(IO2\)](#) - Technology-based and career coaching webinars for in-depth focus on specific issues identified as particularly challenging in the ATMP development cycle to support early-career biomedical scientists in acquiring the knowledge and skills necessary. The existing webinars will remain accessible free of charge on YouTube for viewing. It has been agreed that no new webinar series will be created after the project. However, the European Medicines Agency has expressed their continuous interest to further collaborate on the co-creation of new webinars as well as contributing to the Regulatory unit of the online course. Based on successful results so far further collaboration with the EMA is envisaged beyond the project lifecycle.
3. [Virtual and in-person workshops \(IO3\)](#) - The workshop is a 5-day full time commitment focusing on all aspects of ATMPs development. The curriculum is complemented by career development activities and a site visit to an ATMP manufacturing site. The workshop represents the main activity and the sustainable output of the ADVANCE

project. The workshops will be sustained according to the format further described in this sustainability plan.

4. [Open Badges \(IO4\)](#) - To show the participation in the ADVANCE Programme, digital accomplishment badges associated with participation and acquired skills have been created. The open badges earned by participants will remain visible in the badging environment (Badgr.com) and on the participants' LinkedIn profile (if linked), and the consortium is currently exploring different options to sustain the development of microcredentials after the project.
5. [Sustainability plan \(IO5\)](#) - The sustainability plan describes how the face-to-face course and the online course can be maintained in a way that enables broad participation and reduces the costs for participants.

3. Value Proposition

Advanced Therapy Medicinal Products (ATMPs) are a particularly novel class of medicines and their development possibly constitute one of the most complex organizational and regulatory tasks that may be approached by clinical researchers in order to explore new therapeutic applications. Therefore, there is an important need in Europe to develop educational programs and traineeships to maintain and expand the leadership of our continent in the biomedical sector.

Early career biomedical scientists are considered to be an important component of the labour market and the critical intermediaries of the ATMP development pipeline. The ADVANCE programme strives to educate the next generation of ATMP experts. The ADVANCE blended learning programme supports early-career biomedical professionals in acquiring and developing technical and transversal skills and key competences in four key challenge areas – manufacturing, clinical trials, regulatory approval and reimbursement.

To enable broad participation at reduced costs, the 3-staged blended learning programme was rebranded as the “Cell and Gene Therapy Summer School”, consisting of the free online course and the 5- day face-to-face workshop.

The curriculum of this programme stimulates the acquisition of in-depth multidisciplinary scientific knowledge whilst encouraging the development of personal and transversal skills to help participants boost their confidence and prospects in the labour market. The development of such transversal skills, including communication, presentation, project management, decision-making, networking and entrepreneurial skills, is an integral part of the Cell and Gene Therapy Summer School. Going forward, a certificate will be provided upon completion of the course and where feasible ECTS accreditation will be awarded. Digital badges earned during the lifetime of the ADVANCE project will remain visible on participants' selected media. Career coaching webinars have been integrated in the online course so that participants can still benefit from the learnings from these sessions.

ADVANCE's added value consists of:

- developing multi-competency training (parallel scientific and transversal skills), combining the acquisition of in-depth multidisciplinary scientific knowledge and the development of personal transversal and entrepreneurial skills, tackling identified and currently unaddressed skill gaps in ATMP development;
- providing career coaching, currently not applied in the field of ATMP development and thus innovative, contributing to the recognition and promotion of informal learning which will empower early-career professionals to advance their careers and employability in the field; and focusing on the field of gene therapy, stem cells and tissue engineering, considered to be innovative therapies, opening the door to new treatment approaches for diseases with high-unmet medical need.

As such, the blended learning programme will pay great attention to a good balance between lectures and practical workshops.

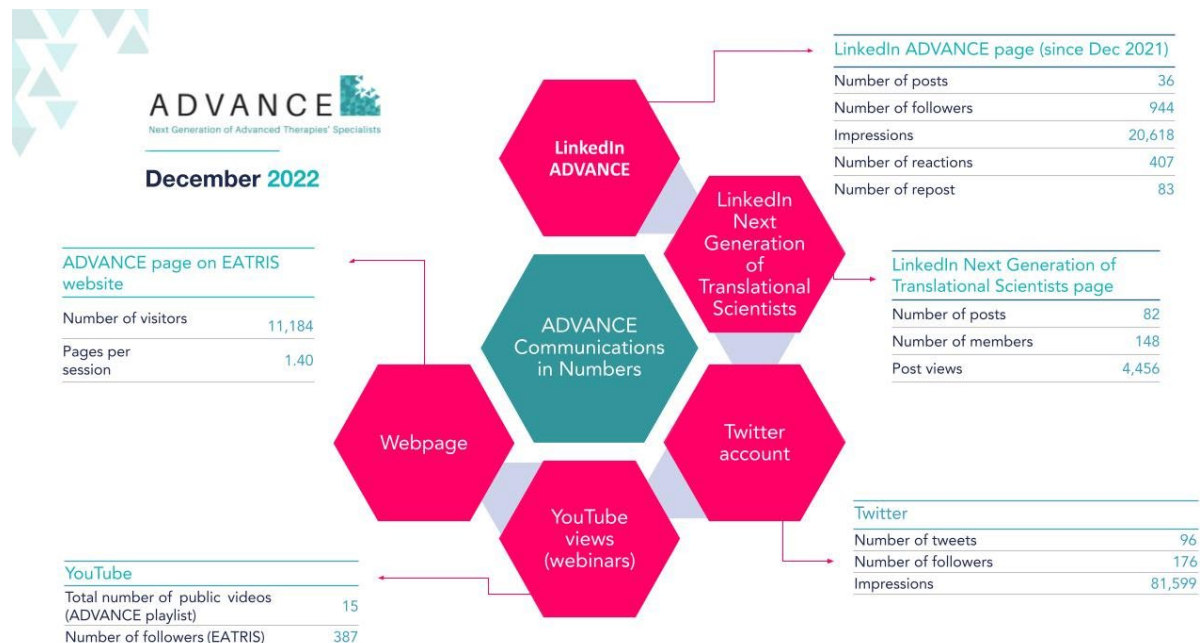
To this aim, the project also envisions to increase the employability of early-career professionals, opening perspectives outside academia by equipping them with the demanded scientific and entrepreneurial skills beneficial for working in biotechnology small- and medium-sized enterprises (biotech SMEs). The blended learning programme will provide better skilled young professionals to the ATMP sector.

4. Marketing strategy

Many European and international organisations and academia offer online training related to healthcare and biomedical specialities. Very few of them offer the opportunity to provide their students career coaching and face-to-face workshops. Compared to traditional training programmes, the development of hands-on, ready-to-use learning including a competency profile for translational medicine, the e-learning course modules and the face-to-face workshop is a unique approach. Additionally, rewarding and recognizing the skills and competencies developed with open badges offer the ADVANCE participants a competitive advantage in the labour market.

Throughout the ADVANCE project, we have developed a solid branding strategy and communication plan. Brainstorming sessions have been organized at the beginning of the project to reflect on the value proposition of the ADVANCE programme and how we could best position ourselves compared to our competitors. As we wanted to include professionals covering all the aspects of Advanced Therapies, we decided to use the word “specialists” and not only focus on “scientists”. During the 3 year project a solid marketing strategy has been defined to create the brand and advertise the e-learning course, webinars and virtual and face-to-face workshops. The training has been advertised through our social media channels, through EATRIS media channels and through the extended networks of the consortium partners.

A summary of our social media and website engagement with our participants and followers is shown in the visual below:



Throughout the project, the ADVANCE Project information has been disseminated through the networks of the consortium partners. Personalised emails to relevant supervisors of PhD students, education and training project leaders, and the education and training community asking to forward the information to interested students have also been sent.

The online course was also listed on the Catapult's [Advanced Therapies Skills Training Network portal](#). The agreement of this collaboration is under revision at the time of writing this plan and will very likely be resumed with the single ownership scheme for the online course, as well as the advertising of the 5-day Workshop in February 2023. The Advanced Therapies Skills Training Network (ATSTN) has been developed as a national (UK) initiative to drive growth across the advanced therapies and vaccine manufacturing industry, through offering access to training facilities and an online training platform which can address the UK's demand for skills. However partners from across the EU are involved in advertising their trainings through the portal.

Optimized branding of the ADVANCE project

As we want to ensure a sufficient number of participants for each of the activities, we have decided to rebrand the name after the end of the project and make the activities more appealing. The ADVANCE programme workshop is now called "Cell and Gene Therapy

Summer School”. This brand also allowed us to better find our target audience as it was realized that ATMP is not as recognizable of a term as “Cell and Gene Therapy.”

In order to optimize the branding of the Summer School and attract the most relevant audience, we are going to focus mostly on the scientific programme. Live career-coaching sessions will not be held going forward, however career coaching videos have been integrated in the online course.



Competitor Analysis

A competitor analysis suggests that one of the ADVANCE program’s strengths lies in its target audience. Other ATMP training courses are geared towards training established industry professionals and actors within the ATMP space, whereas the ADVANCE programme is structured to offer opportunities to PHD students, post-docs, and early-stage professionals. The ADVANCE programme does not only teach scientific and industry knowledge in relation to ATMPs, but it also offers training on soft-skills and networking opportunities, complemented by career coaching, which are attractive elements for its unique target audience. Additionally, the ADVANCE programme is focused on the European space and the in-person workshops take place in Europe, whereas other competitors offer in-person training in the US and UK. Another trait that sets the ADVANCE programme apart from competitors is its hybrid online and in-person course structure. Finally, the proposed pricing scheme of the ADVANCE programme seems to be relatively inexpensive when compared to offers of the competitors.

Market analysis during the project was carried out as well (see Annex 2). Previous analysis allowed us to position ourselves on the market while running the project.

Feedbacks from participants

The project focused on assessing the quality of the training provided and conducted regular evaluations of both the online and the workshops throughout the project's duration. Such regularity was critical for assessing our level of success and the progress made throughout the project's lifetime.

Online course

The online course reached almost 1000 participants, with a completion rate of 11.0%, which is considered a good rate for online courses. Considering the specificity of the contents, the completion rate is considered very good. Overall rating was very high, with 8.5/10 on average for the entire course. The regulatory unit scored highest with an 8.5, followed by both the scientific and manufacturing learning units (8.4/10) and the final unit on pricing and reimbursement was scored with an 8.0/10

5-day workshop

Overall rating (on a scale of 1 (poor) to 10 (excellent)) of the 5-Day workshop was 9/10 for both the virtual edition (2021) and the in-person edition (2022). All respondents would recommend the course to their peers (100%).

Lecturers were very well rated (good to very good) and all additional activities were much appreciated, e.g. the 3 min pitch talks, group work and post lecture discussions. The in person workshop had additional benefits over the virtual edition, e.g. the facility tour, social activity and networking with peers and speakers were highly rated.

Suggestions provided by the participants from both the online course and workshop helped the consortium improve the quality of the second cycle of courses.

Impact surveys of the workshops

To assess impact of the blended learning programme, additional metrics were captured in a follow-up feedback survey (see Annex 2), assessing to what extent envisaged results and impact set out at the beginning of the project were met, mainly regarding the effects on the participants' competencies and career perspectives, as well as on their daily work and professional network.

Additionally, the survey collected input for the sustainability plan, assessing participants' thoughts on pricing and duration of the course and the importance of support and/or hosting by industry.

In general the response rate to impact surveys (typically collected 6-12 months after the completion of the activity) is fairly low. This is also in line with the response rate for ADVANCE 5-Day workshop impact survey.

Outcome of the impact surveys (Virtual and in-person) workshop

The 2021 Virtual Workshop impact survey was launched 8 months after the workshop to all 26 participants. Although feedback was positive, the survey collected only 4 responses. For the 2022 in-person workshop, the survey was performed 6 months after the workshop to 31 participants and 13 responses were collected. Below is a brief summary of the outcome of the survey

Areas in which the workshop positively Influenced the participants career was as follows

1. Increased collaborations
2. Increased recognition in their sector
3. Found a new opportunity in industry
4. Found a new opportunity in other sectors
5. Gained knowledge through active participation of peers

The tools, lectures and approaches learned at the workshop contributed a great deal to a good panoramic vision and better understanding of the different aspects and developmental phases of the ATMP field, helping participants to critically assess the characteristics of an ATMP and structure their project moving forward. The workshop helped them in the decision making process thereby boosting their self-confidence and helping them to navigate the regulatory world by pointing them towards helpful tools.

The workshop also increased participants' ability to develop collaborations and or/ expand their network, e.g by providing for new job opportunities, sharing of information and ideas or developing new collaborations. Especially those attending the in-person workshop, mentioned that meeting with and talking to experienced people was very beneficial to them and that they felt they could now more easily approach them, when looking for a collaboration.

For the sustainability of the workshop, participants were asked to share their thoughts on the future pricing and duration of the course and the importance of support and/or hosting by industry. For the pricing, most participants answered positively regarding the willingness to pay a fee for the course, and mentioned a fee ranging from 300€ up to 750€, in addition to travel costs for attending the workshop.

With regards to missing time at work and other commitments, we asked participants if they would have preferred a different time schedule. Most of the participants preferred the Monday-Friday time schedule, only 1 answered the preference of a shorter course (3 days with less content).

The fact that the in-person workshop was hosted on the premises of a biotech company was considered to be very important to most of the participants of the survey, others mentioned this was a nice experience but not essential. Overall, the involvement of industry in the workshop was considered key and a major added value for the course, as well as the presence of the regulators and EMA.

Impact and opportunities

1. **Online course:** Attending the online course will improve learners' common knowledge of the ATMP development cycle and the different multidisciplinary barriers encountered in ATMP development. Moreover, more participants will have the chance to enhance their knowledge free of cost and at their own pace.
2. **Webinars:** The webinars serve as multipliers and advertising for the course, potentially triggering a broader public for online course participation.
3. **Face-to-face workshops:** A deep dive curriculum for an intensive study programme for early-stage biomedical researchers involved in ATMPs development including both scientific and transversal skills to help overcome the multidisciplinary barriers encountered in ATMP development cycle and job market.

The impact on the course participants is their improved employability in the ATMP field not only through the development of technical and soft skills, but also through the introduction to an international and interdisciplinary ATMP network. The career coaching component of the program is important in boosting the participants' confidence, knowledge around different career tracks and chances in the labor market. Since the next generation of ATMP young professionals are a critical component of the ATMPs development pipeline, this will help achieve the project's ultimate goal to improve human health.

The impact on the participant organisations is their students being trained with skills demanded by the labor market in the ATMP field. Additionally, being part of a network of organisations in translational research ensures that education, research, and innovation are brought together. The partnership also promotes important collaborations with ATMP stakeholders such as HTA bodies, regulators, pharmacists, and patient representatives, in order to achieve the ultimate goal of faster, safer, and affordable treatments for patients with unmet medical needs.

The envisaged impact for the Biomedical community in Europe and beyond is:

- increased interaction between stakeholders in research, education, and innovation through joint development of curriculum

- international and interdisciplinary knowledge exchange, networking, and mutual support through bringing together a cohort of participants with different backgrounds
- increased geographical and public/private sector mobility
- European competitiveness in Medicines Development is ensured through the delivery of skills, including entrepreneurship
- Improvements in human health due to better trained professionals

Impact at local and regional level:

- Course participants integrate the course into their local and regional communities
- Curriculum is available for any university, research or other organisation, enabling them to provide relevant courses locally and regionally.
- No access barrier to the free of cost self-paced material is especially beneficial for participants from the countries classified by the EU as lower innovation and research performing

2. Risks and quality assurance

Consortium and output risk management

1. **Risk of Online course:** The major risk is the already existing wide offering of online courses. It is difficult to stand out and make the voice heard in an otherwise oversaturated landscape of MOOCs. This was heightened by the COVID-19 pandemic, where many institutions were forced to move online, which created an even wider offering.
2. **Webinars:** A major risk relies on the identification of our target audience. Indeed, as we could have seen with YouTube view and webinars' registration, many students followed the career coaching webinars, even though they were not part of the biomedical field. Therefore, we experienced a big fall of views and participants for the technical webinars. The challenge is to attract further specific audience.
3. **Face-to-face workshops:** The major risk concerns the sustained (financial) engagement of the whole consortium after project funding.
4. **Internal risks after the project:** We have identified the following internal risks:
 - a. During the project: turnover of human resources within the consortium
 - b. After the project: partners redefining their strategy and become competitors to the ADVANCE project
 - c. Given the fact that the new consortium taking over at the end of the project will be smaller, we expected our internal risks to be decreased
5. **The COVID-19 crisis** has had an impact on higher education in general. It has forced us to adapt the ADVANCE project, both in the organization of the programme and the management of the participants, as well as in the project management with the

partners. The pandemic has highlighted the challenges and opportunities for the global health system and created a critical need to transform various aspects of medical education to reflect the changing medical landscape. Mobility restrictions for participants forced us to adopt a 100% online learning, including for our workshop originally planned in Rome. One of our strengths was the blended learning we offered to our participants. We had to be creative to create and promote a week-long programme that combined lectures, teamwork, workshops, and participant engagement. Thanks to our collaborative efforts, we created a well-balanced programme for the week (see workshop programme in the Annex). Thanks to the active mobilization of all partners, 24 participants have enrolled and completed the 5-day workshop. The participants responded positively to the proposed program. The pandemic has truly posed a challenge for the smooth running of the project and for the collaborative work of the European partners.

Product risk management

The 2 main outputs/ products that will be sustained under the project going forward are the Online Course, and the 5-Day Workshop. Risks associated with the online course sustainability are minimal, as it will be integrated to EATRIS online learning management system TranMed Academy. For the 5-Day Workshop we have defined several go and no go criteria for the continuity.

The first risk is associated with attracting a sufficient number of participants. It is envisioned that 30 participants is the ideal number for the workshop. The minimum registrants would be 20 participants. In this case, the consortium together with the potential host will make a go/no go decision. In this scenario, the consortium will have to look for an additional sponsor(s) to compensate for the missing income.

In the case that less than 20 participants are recruited for the workshop, it will be cancelled and an alternative date will have to be provided.

In any case, the consortium and potential sponsor will also ensure that there are no conflicts with other major ATMP events or conferences in Europe at the same time.

Other identified risks

Under our risk management strategy, we could also highlight the following risks as potential threats to the organization of the workshops:

- Continuous increase in travel costs and energy prices
- Further pandemic preventing participants and experts to join
- Host cancellation on short notice

- Failure to secure sponsors/sufficient funding and contributions (i.e free of cost event venue)

3. The Sustainability Plan

1. Business organisation

a. Role of the consortium partners

The ADVANCE Consortium consists of 7 European partners. Each partner was responsible for an intellectual output throughout the ADVANCE Project:

- E learning course curriculum (IO1) - ELEVATE
- Webinars (IO2) - KU Leuven
- Workshops curriculum (IO3) - ISS & UL-FFA
- Open badges development (IO4) - EATRIS
- Sustainability Plan (IO5) - I3h, ULB
- TAKIS to provide input to IO1, IO2, IO4 and IO5

Each partner has nominated a primary contact who was responsible for disseminating relevant information within her/his team and more broadly within her/his organization or university.

b. Resources/support

During and after the end of the project, our aim is to provide our blended-learning training to our targeted customer segment, PhDs and young postdocs in the field of ATMPs development.

In the table below, the resources needed to establish our business and keep the ADVANCE learner's journey alive are identified.

Our training has only a limited number of seats available for the face-to-face workshop. We can therefore state a clear request for key resources as the demand as such will not increase.

For the Online course

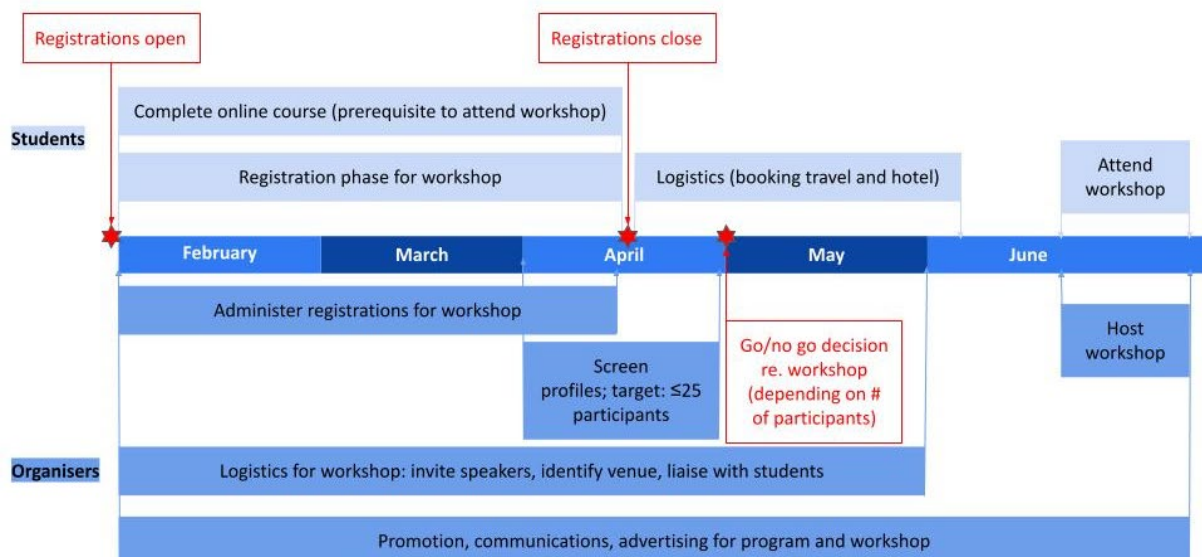
Financial	Physical/logistics	Intellectual	Human
Creation of communication materials	The online course will be available on the TransMed Academy based on the Moodle-based LMS platform. This is an open-source platform.	The course has been established during the ADVANCE project. The content of the course will not be renewed.	IT maintenance of the platform A large distribution network across Europe is required. The consortium team as well as the sponsor will use their

	EATRIS will thus own the course and make it available to the public free of charge.		contacts to advertise the offered training.
--	---	--	---

For the Face-to-face workshop

Financial	Physical	Intellectual	Human
<ul style="list-style-type: none"> Experts Coordinators Google Drive storage Moodle environment for the participants' management Communication officer Administrative support 	<p>15 experts and 3 coordinators have participated in the creation of our face-to-face workshop.</p> <p>The venue will accommodate at the same time at least 25 participants, 3 coordinators and 1 lecturer.</p> <p>Technical equipment is also needed: microphones, beamer, blackboard, chairs, pens, paper, printer, pins for the posters and a laptop for the workshop presentations, etc.</p>	<p>The content will have to be checked and renewed every year. We aim to have at least 15 different lectures, 7 group work sessions and elevator pitches and 1 committee of evaluation.</p>	<p>A large distribution network across Europe is required. The consortium team as well as the sponsor will use their contacts to advertise the offered training.</p>

c. New learner's journey



The ADVANCE Project has been run in cycles. As mentioned above, the online course will remain a prerequisite for the workshop. Workshop will only be run once a year.

d. Legal framework and ownership

The ownership of the face-to-face workshop will stay within the consortium. We have identified a new model for the organisation of the next editions of the ADVANCE 5-Day Workshop. The new model is based on joint ownership and a rotational organization between Takis Biotech and ISS in Italy, EATRIS ERIC in Amsterdam and UL FFA in Slovenia. For this, an ownership transfer agreement will be set up between consortium partners.

According to the information available at the time of writing this plan, the workshop is planned to be held in Ljubljana in 2023. The course will be organised at the University of Ljubljana, Faculty of Pharmacy and the facility tour will take place in a biotech partner.

In 2024, we plan to have the workshop in the Netherlands and in 2025, Takis will take over the organisation of the workshop.

As explained before, the MOOC (Massive Open Online Course) titled: “ADVANCE ATMP Development ” (IO1) was created (hereinafter “the Online Course”). All consortium partners have agreed to vest the full ownership of the Online Course, including associated industrial and intellectual property rights, to EATRIS ERIC.

EATRIS ERIC shall exercise its best efforts to make the Online Course available to the public, free of charge, upon the end of the Project and beyond. The agreement was signed by all parties before the end of the project (31/12/2022).

The ownership of the webinars (as created during the project life cycle) will stay within the consortium, the videos will remain hosted for free on EATRIS YouTube Channel (organised into ADVANCE Playlist).

2. Cost structure

Online course

Item	How often?	# of participants	Cost
License and hosting (no additional cost as the course are hosted on EATRIS platform)	1/year		€300

Maintenance and technical support (including updating)	On regular basis	up to 200	€300
Total online course costs			€600

As the online course will be sustained on the EATRIS platform, we have not foreseen any cost on licensing and hosting. Furthermore, it is not foreseen to update the content of the online course. No new online course will be developed in the context of the ADVANCE project. However, participants will have the opportunity to access the other new courses available on the platform. The price includes the management of 200 participants.

Face-to-face workshop

Item	Who?	# of participants	Cost
Organisation: Room rental, marketing actions, staff cost preparation, transfer and Rome tour	Host	30 participants + 15 organisers	€ 10 862
Lecturers costs	Organiser	2 lecturers	€ 890
Catering	Host	30 participants + 15 organisers	€ 8 440
Total workshop costs			€ 20.192

The full cost breakdown is developed in Annex 3.

a. Mixed financing of the workshop and online course

We have evaluated the yearly cost at 21.000 Euros.

To cover the costs of running the face-to-face workshop, we will charge our participants with a registration fee. As the online course and the webinars will remain free of charge, the revenues will only come from the workshop participants.

The online course will remain a prerequisite for participating in the workshops. As the online course will be hosted on EATRIS educational platform, no cost has to be foreseen.

In order to lower the participants' fee, the consortium will do its best efforts to find a sponsor willing to take care of key expenses in exchange for a few free seats for their own employees.

b. Payment schemes (industry vs academia)

Based on the assumption that we will attract a maximum of 30 participants to our workshops, our proposition to be sustainable after the end of the project is the following:

- Members of the consortium: 475 euros
- Academia or affiliation with a university: 650 euros
- (Junior) Professionals/SME's: 750 euros

We have decided to apply the described payment schemes. Indeed, we are convinced that these prices reflect the value and the level of expertise of the programme. As our aim is not to generate profits, the potential extra money will be used for the next year's edition to cover organisational costs such as catering, venue rent, networking activities for the participants (but not staff cost).

Based on our experience in organising the 2 previous workshops, we are convinced that 30 participants is enough to attract a variety of profiles (staff research from biotechs, people working in regulatory, PhD students, Post-Docs and clinical people, medical doctors, etc) and remains feasible from a logistical point of view (organisation of the biotech tour for example).

In order to offer the ADVANCE Programme at the best possible costs, we have considered the following ways to potentially reduce our costs:

- Organize the workshop in a central location so as to reduce transfer costs
- Take out group dinner
- Organize a 4-day workshop instead of 5 days
- Take out group tour
- Make the best use of available internal resources as a way of decreasing staff cost preparation

c. Hosting and financial support of the workshop

We will reach out to biotech/pharmaceutical companies for financial support or hosting of the workshop. In return, these companies will have access to a viable candidate pool of young professionals and scientists in the ATMP space. Additionally, we can include real case studies or projects of the company for the ADVANCE students to work on as part of the program, providing an additional hands-on benefit to both the company as well as the students. Potential companies to contact include those with EMA approved cell and gene therapies.

3. Business opportunities and partnerships

The 4 pillars of the curriculum of the ADVANCE programme will remain the same: scientific, manufacturing, regulatory approval, and reimbursement. An emphasis will also be put on patients' representation. Market research amongst partner organisations and affiliated graduate schools will be performed to investigate the interest for integrating the developed activities in existing training programmes.

Synergies and other collaborations

One of the synergies that we have explored during the ADVANCE programme is our collaboration with the European Medicines Agency. They showed clear interest to engage in further activities. 2 webinars have been co-organised with EMA. These webinars have attracted 660 participants and allowed us to reach new target groups.

If we charge our participants for the ADVANCE programme, we will inform our external partners about the non-profit objective of the ADVANCE programme and we will make sure that the extra money will only serve the ADVANCE project and will be reinvested for communication activities and for improving our workshops.

Potential external funding

The Innovative Health Initiative is an EU public-private partnership funding health research and innovation. One of their draft topics on future calls for funding is entitled “[Strengthening the European ecosystem for Advanced Therapy Medicinal Products \(ATMPs\) and other innovative therapeutic modalities for rare diseases](#)” which is a great fit for the ADVANCE program.

Potential funders in the Netherlands, where EATRIS is based, include Stichting DOEN and the Dutch National Postcode Lottery, which has one focus area on [well-being and health](#).

Another alternative source of support is the Marie Skłodowska Curie Action, EATRIS ERIC is currently in process of developing a proposal that if successful would allow to organise one edition of the 5-Day workshop in 2024 or 2025 provided that the agreed 10 seats are reserved for students entering the MSCA fellowship program. The results of this proposal’s success will be known in early 2023.

Another grant proposal on advanced therapies is currently under development by partners from UL FFA. If successful, a 3-year project will be funded by University of Ljubljana, NOO project grant, starting in the beginning of 2023.

4. Conclusion

ATMPs offer unprecedented promise for the long-term management and even cure of diseases, especially in areas of high unmet medical need. For ATMPs to fulfil their potential, specific skills and knowledge in four key areas need to be available in the workforce, which are currently lacking: manufacturing, clinical trials, regulatory approval and reimbursement.

The ADVANCE programme has set out to bridge this skill gap by training early career biomedical professionals, thereby enhancing the skills and knowledge available in the biomedical science labour market. The longer-term benefit of this project will be

improvements in public health due to better trained professionals, who drive effective and accelerated ATMP development.

Participants have emphasised the impact the programme had on their careers by increasing their employability thanks to enhanced knowledge and skills related to ATMPs. They also noted the positive influence of the programme's collaboration and networking opportunities. This provides benefits not only to individual participants, but also contributes to increased mobility and interaction between different sectors and countries for the whole ATMP field.

Based on the results of the project, feedback from participants, and lessons learned, the consortium is well-prepared to optimise the next iterations of the programme and is highly motivated to sustain the outputs of this project and carry out the above-mentioned plan.

5. Annexes

Annex 1: Dissemination and Communication Plan

Annex 2: Market analysis

Annex 3: Cost breakdown